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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,784	01/26/2006	Anders Larsson	LARSSON4	9326

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
08/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,784	LARSSON ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-40* is/are pending in the application.

4a) Of the above claim(s) *25-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-24, 39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2008 has been entered.

Claims 1-19 and 41 have been canceled.

Claim 20 has been amended.

Claims 20-40 are pending in the instant application.

Claims 25-38 stand withdrawn from consideration as being drawn to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03, for reasons of record set forth in the restriction requirement mailed February 7, 2007.

Claims 20-24, 39 and 40 are under examination as they read on pharmaceutical compositions comprising IgY antibodies that bind *Enterobacter cloacae*.

Specification

2. The title is objected to as not being specific for the instant claimed subject matter. A new title that accurately reflects that which is instantly claimed is suggested.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 20-24, 39, and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Colman et al. (WO 98/14209, of record) in view of Boccia et al. and in view of Carroll et al. (US Patent 5,599,539) for the reasons of record.

The office action mailed May 24, 2007 states:

> Colman et al. teach compositions comprising avian antibodies (i.e. IgY) that are to be used to treat enteric infections in immunocompromised patients such as neonates (see entire document, particularly the abstract, lines 1-18 of page 2, and lines 6-32 of page 8). They disclose that passive immunization (i.e. administration of preformed antibodies to a patient) has been shown to protect individuals from neonatal necrotizing enterocolitis (see particularly lines 8-12 of page 6 and lines 24 and 25 of page 9). The avian antibodies are disclosed as being administered in a multitude of forms, including as part of a nutritional formula given to patients in an intensive care unit (see particularly pages 14 and 15, most particularly lines 28-30 of page 15). These teachings differ from the instant claimed invention in that Colman et al. do not disclose that their avian antibodies are specific for antigens found in *E. cloacae*.
>
> Boccia et al. teach that necrotizing enterocolitis is one of the most serious gastrointestinal diseases among newborns, that it mainly affects newborns in intensive care units, and that *E. cloacae* is an important causative agents for this disease (see entire document, particularly the abstract and Table 3).
>
> Carroll et al. teach that avian antibodies are to be mixed with infant formula for ease of administration to infants (see particularly lines 45-61 of column 3).
>
> Therefore, it would have been obvious to a person of ordinary skill in the art at the time the instant invention was made to make a composition comprising IgY that is specific for *E. cloacae*. Motivation to do so comes from the teachings of Boccia et al. that *E. cloacae* is a major pathogen in neonatal intensive care units that causes necrotizing enterocolitis and the teachings of Colman et al. that antigen specific IgY is to be used to treat diseases such as neonatal necrotizing enterocolitis. A skilled artisan would have been further motivated to place the *E. cloacae* specific IgY antibodies into infant formula based on the teachings of Colman et al. that their antibodies are to be added to nutritional supplements given to intensive care patients and the teachings of Carroll et al. that IgY is to be added to infant formula for ease of administration to infants.

And the office action mailed December 10, 2007 states:

> Applicant's arguments filed October 24, 2007 have been fully considered but they are not persuasive. Applicant's first argument is that the statements made by Coleman et al. concerning the absorption of IgY from the intestines and transport through the circulatory system are unsubstantiated.
>
> This argument is not relevant because as disclosed by Boccia et al., *E. cloacae* causes enteric disease. Orally administered antibodies are delivered directly to the gastrointestinal tract which is the site of infection and thus there is no need for the antibodies to go elsewhere in the body. Passive immunization by administering antibodies, including IgY, to protect against enteric infection is well known in the art. See particularly lines 8-38 of Colman, as well as Yokoyama et al., Ikemori et al., Zuniga et al., Peralta et al., and note that many of these provided references were cited by Colman et al. As such the disclosed speculation concerning IgY absorption is not relevant and a person of ordinary skill in the art would expect that passively administered IgY antibodies protect against enteric infections.

> Applicant's second argument is that Coleman was convicted of misdemeanors under the Food, Drug, and Cosmetic Act, and therefore no one would believe the disclosure of the WO 98/14209 publication by Colman et al.
>
> This argument is not persuasive because the examiner need not consider actions taken in another judicial proceeding and jurisdiction with regard to patentability of the instant application under United States law. The criminal/civil procedures relied upon applicant has no relevance to determine of whether the same invention would have been obvious to one of ordinary skill in the art at the time the invention was made within the ambit of 35 USC 103(a). Further, based upon the prior art cited in the Colman et al. document, a person of ordinary skill in the art would definitely believe that enteric infections can be treated by passively administering IgY because this is precisely what has been demonstrated to work by other researchers as discussed above. Specifically, applicant states that there is "no substantiation for the allegation that avian antibodies can actually be used to treat enteric infections in immunocompromised patients." Note that in 1992 Yokoyama et al. disclosed "Passive Protective Effects of Chicken Egg Yolk Immunoglobulins Against Experimental Enterotoxigenic *Escherichia coli* Infection in Neonatal Piglets", that this work was cited by Coleman et al., and that neonates are immunocompromised (see particularly lines 9-17 of page 4 of the instant specification). Therefore it appears that applicant's statement concerning avian antibody efficacy is incorrect in view of the teachings of the prior art.
>
> Applicant also argues that "Carroll teaches that avian clostridial antitoxin, not avian antibodies, can be mixed with infant formula for ease of administration to infants."
>
> This argument is not persuasive because clostridial antitoxin is avian polyclonal antibodies. Applicant is invited to review the Description of the Invention found in columns 4 and 5 of Carroll et al. wherein it is disclosed that the antitoxin is made by immunizing chickens, as well as working Examples 1-7 of Carroll et al.
>
> Note that new claims 40 and 41 have been joined to this rejection. Claim 41 is an exact duplicate of claim 24. Claim 40 recites that said nutritional agent is human breast milk or a substitute thereof, and infant formula is a substitute for breast milk. As such, the limitations recited in the new claims have been previously addressed in the rejection of record.

Applicant's arguments filed June 10, 2008 have been fully considered but they are not persuasive. Applicant argues that the claims have been amended to recite that the compositions are to be used to treat infections caused by *Candida albicans* and that no working examples of administering IgY to humans are found in the cited references.

These arguments are not persuasive. First, the instant claimed invention is a product. The recitation of an intended use, in this case, "for treating enteric infections of *Candida albicans* in humans" in a product claim does not provide patentable distinctiveness unless the intended use necessitates a change in the structure of the product. See MPEP 2111.03. In the instant case, the intended use recited in the claim in no way alters the physical form of the claimed composition.

Applicant's other argument is that no working example has been cited wherein IgY has been administered to a human patient. It should be pointed out that applicant is claiming a product, not a method. Any motivation to make a product, even if different from applicant's own motivations, would be sufficient to render the invention obvious. It should also be pointed out that ever since humans have been eating avian eggs, they have been consuming IgY. Clinically effective passive immunization via oral

administration of IgY is well known in the art, having been performed on a wide variety of laboratory and livestock animals including mice, rats, rabbits, pigs, calves, and chickens, as has been discussed in prior office actions with regards to the art disclosed by Colman et al., Carroll et al., Yokoyama et al., Ikemori et al., Zuniga et al., and Peralta et al. Further, effective human administration was also demonstrated in the art prior to the filing of the instant application. See for example the article by Sarker et al. titled "Randomized, Placebo-Controlled, Clinical Trial of Hyperimmunized Chicken Egg Yolk Immunoglobulin in Children With Rotavirus Diarrhea", US Patent 6,537,550, and WO 98/41235. As such, oral administration of IgY, including administration to humans, was known to be effective at the time the instant invention was filed, and as such this art area cannot reasonably be considered unpredictable. Thus applicant has applied a known technique to a know problem to obtain a predictable solution.

The rejection is maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20-24, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has amended independent claim 20 to recite that pharmaceutical compositions comprising antibodies that are specific for *E. cloacae* are to be used in treating *Candida albicans* infections. The specification discloses administering *E. cloacae* specific antibodies to treat infections caused by *E. cloacae.* Similarly, it also discloses administering *C. albicans* specific antibodies to treat infections caused by *C. albicans.* The specification does not disclose prophetic or actual working examples

wherein *E. cloacae* specific antibodies were administered to patients to treat infections caused by *C. albicans.* Also, it is known in the art that antibodies are antigen specific such that they bind a specific antigen and do not stochastically bind other antigens of unrelated sequence and structure (Janeway et al., see entire document). Further, *E. cloacae* and *C. albicans* are distinct microorganisms that are not highly related. As such, it is not reasonable that antibodies specific for *E. cloacae* would bind to *C. albicans* and thus be effective for treating infections caused by *C. albicans.*

Therefore, in view of the breadth of the claims, the lack of working examples, and the teachings of the art, a skilled artisan would be unable to make and use applicant's compositions as currently claimed.

7. Claims 20-24, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended independent claim 20 to recite that pharmaceutical compositions comprising antibodies that are specific for *E. cloacae* are to be used in treating *Candida albicans* infections. The specification discloses administering *E. cloacae* specific antibodies to treat infections caused by *E. cloacae.* Similarly, it also discloses administering *C. albicans* specific antibodies to treat infections caused by *C. albicans.* The specification does not disclose administering *E. cloacae* specific antibodies to treat infections caused by *C. albicans.* As such, applicant's claim amendments received June 10, 2008 have broadened the scope of the invention beyond that which is present in the specification as filed. This broadening of the application is new matter. In response to this office action, applicant should either delete the new matter from the instant claims or point out where explicit support for the invention as presently claimed is located in the instant specification.

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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